

## Message Text

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ACTION OES-09

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FOR OES/ENP/EN, WILLIAM WALSH; INR/OIL

DEPT PASS TO NIH/FIC FOR DR. QUINN; NSF

E.O. 11652: N/A  
TAGS: TBIO, JA  
SUBJECT: RECOMBINANT DNA RESEARCH GUIDELINES

REF: (A) 77 TOKYO 11845, (B) 77 TOKYO 9460

1. ON JULY 24, THE SPECIAL COMMITTEE ON SCIENCE AND SOCIETY (CHAIRMAN: PROFESSOR JUNICHI AOMI OF UNIVERSITY OF TOKYO) OF THE SCIENCE COUNCIL, MINISTRY OF EDUCATION, SCIENCE AND CULTURE, ANNOUNCED DRAFT GUIDELINES ON RECOMBINANT DNA RESEARCH. THE DRAFT GUIDELINES REMAIN TO BE APPROVED BY THE SCIENCE COUNCIL. COMMENTS ON DRAFT GUIDELINES WILL BE SOUGHT FROM VARIOUS QUARTERS IN THE NEXT THREE TO FOUR MONTHS BEFORE THEY ARE SUBMITTED TO THE SCIENCE COUNCIL AND, IF APPROVED, TO THE MINISTER OF EDUCATION, SCIENCE AND CULTURE. THE MINISTER WILL THEN OFFICIALLY ANNOUNCE THE GUIDELINES FOR ENFORCEMENT.

2. THE DRAFT GUIDELINES WILL APPLY TO RESEARCHERS RECEIVING SCIENTIFIC RESEARCH GRANTS FROM THE MINISTRY OF EDUCATION, SCIENCE AND CULTURE, BUT THE COMMITTEE HOPES  
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THAT THEY WILL BE OBSERVED BY RESEARCHERS IN GENERAL AS JAPAN'S PUBLIC GUIDELINES REGULATING RECOMBINANT DNA RESEARCH. GUIDELINES FOR RESEARCHERS BELONGING TO NATIONAL RESEARCH LABORATORIES UNDER MINISTRIES OTHER THAN THE MINISTRY OF EDUCATION, SCIENCE AND CULTURE AND FOR THOSE BELONGING TO PRIVATE ENTERPRISES WILL BE FORMULATED BY THE COMMITTEE ON THE LIFE SCIENCES OF THE PRIME MINISTER'S

COUNCIL FOR SCIENCE AND TECHNOLOGY (CHAired BY PROFESSOR TAKASHI FUJII) BY THIS AUTUMN ALONG THE LINES OF THE DRAFT GUIDELINES OF THE MINISTRY OF EDUCATION, SCIENCE AND CULTURE.

3. THE BASIC IDEA BEHIND THE DRAFT GUIDELINES IS THAT JAPAN SHOULD GO ALONG WITH OTHER COUNTRIES IN THE CONDUCT OF RECOMBINANT DNA RESEARCH. THEREFORE, THE GUIDELINES AS DRAFTED BY THE SPECIAL COMMITTEE ARE VERY MUCH LIKE THOSE OF THE U.S. AND EUROPEAN COUNTRIES.

4. THE DRAFT GUIDELINES CALL FOR THE CENTRAL GOVERNMENT TO ESTABLISH A "CENTRAL COMMITTEE" COMPOSED OF EXPERTS IN VARIOUS DISCIPLINES TO ENSURE COMPLIANCE WITH THE GUIDELINES AND A "RECOMBINANT DNA RESEARCH CENTER" TO PERFORM PIONEERING BASIC RESEARCH IN BIOLOGY. THE DRAFT GUIDELINES ALSO CALL FOR EACH UNIVERSITY AND RESEARCH LAB TO SET UP A "SAFETY COMMITTEE" TO ENSURE SAFETY OF EXPERIMENTS AND TO APPOINT A PERSON RESPONSIBLE FOR SAFE CONDUCT OF RESEARCH. THE CENTRAL COMMITTEE, TO BE PLACED UNDER THE SCIENCE COUNCIL, WILL REVIEW RESEARCH AND EXPERIMENT PLANS SUBMITTED BY RESEARCHERS AND WILL ALSO DELIBERATE UPON LONG-RANGE PROGRAM FOR GENETIC ENGINEERING RESEARCH AND REVISION OF THE GUIDELINES. NO EXPERIMENTS USING DNA OF CARCINOGENIC AND PATHOGENIC GERMS AND VIRUSES OR NO EXPERIMENTS WITH HIGH BIOHAZARD POTENTIALS

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SHALL BE CONDUCTED WITHOUT SPECIAL REVIEW AND APPROVAL BY THE CENTRAL COMMITTEE.

5. BASICALLY THE DRAFT GUIDELINES INCORPORATE THE SAME METHODS OF REGULATION AS OTHER COUNTRIES, BUT THEY ARE CHARACTERIZED BY THE FOLLOWING: (A) THE DRAFT GUIDELINES INCORPORATE STANDARDS PREPARED BY A VOLUNTARILY ORGANIZED GROUP OF SCIENTISTS; (B) GREAT POWERS ARE TO BE EXERCISED BY THE CENTRAL COMMITTEE TO ENSURE THE SAFETY OF RESEARCH AND EXPERIMENT; (C) RESEARCHERS AND UNIVERSITIES ARE DIRECTLY RESPONSIBLE FOR THE CONDUCT OF RECOMBINANT DNA RESEARCH; AND (D) THE GUIDELINES ARE TO BE REVISED IN LIGHT OF THE PROGRESS OF RESEARCH.

6. THE EMBASSY HAS OBTAINED A COPY OF THE SPECIAL COMMITTEE'S REPORT CONSISTING OF A SUMMARY OF REPORT, TEXT OF REPORT AND THE DRAFT GUIDELINES. MINISTRY OFFICIALS TOLD EMBOFF THAT THEY PLAN TO PUBLISH ENGLISH VERSION OF REPORT BY SEPTEMBER FOR CONVENIENCE OF FOREIGN RESEARCHERS. THEY ALSO SAID THAT REPORT IS INTERIM IN NATURE AND WILL BE REVISED IF NECESSARY. BY REVISION THEY APPARENTLY MEAN RELAXATION OF REGULATION. THEY ARE PARTICULARLY INTERESTED

IN DEVELOPMENTS IN THE U.S. AND ARE PREPARED TO INTRODUCE  
MODIFICATIONS IN DRAFT GUIDELINES IF AND WHEN NIH ANNOUNCES  
FURTHER REVISIONS IN ITS CURRENT GUIDELINES. MANSFIELD

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